(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 836 835 A2

# (12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
**22.04.1998 Bulletin 1998/17**

(51) Int Cl.[6]: **A61B 17/70**

(21) Application number: **97308140.9**

(22) Date of filing: **14.10.1997**

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE**
Designated Extension States:
**AL LT LV RO SI**

(30) Priority: **18.10.1996 US 734520**
**01.04.1997 US 831112**

(71) Applicant: **Spinal Innovations**
**Cordova, TN 38018 (US)**

(72) Inventor: **Richelsoph, MARC**
**Memphis,TN 38133 (US)**

(74) Representative: **Davies, Gregory Mark**
**Urquhart-Dykes & Lord**
**Alexandra House**
**1 Alexandra Road**
**Wales**
**Swansea, Wales SA1 5ED (GB)**

## (54) Spinal implant fixation

(57) A spinal implant fixation assembly includes a bone fixation member, such as a screw or hook for fixation to a bone. A rod receiving seat is operatively connected to the bone fixation element for seating a portion of a rod therein. A locking mechanism, in the form of a nut and locking ring engage the rod receiving seat for forcing an inner wall of the rod receiving seat to contour around and engage the rod seated therein and for locking and fixing the rod relative to the inner housing. In one embodiment, the locking ring secures a head portion of the bone fixation element within the assembly. A method is also provided for locking the rod to a bone by fixing a rod seating member to a bone and seating a portion of a rod within a substantially U-shaped seat of the seating member. The rod is then locked within the U-shaped seating member while engaging and contouring at least a portion of the U-shaped seat about the rod. The assembly further includes a screw head receiving insert for obtaining a head of screw therein. The insert is moveable within the assembly between a locked position entrapping the screw head and an unlocked position wherein the screw head enters or escapes.

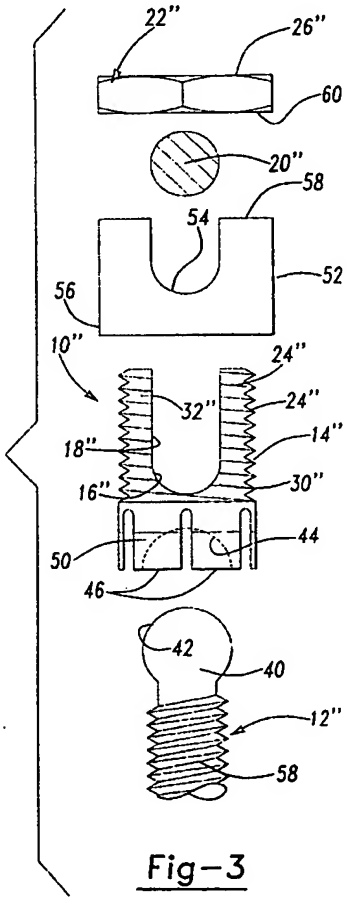



Fig-3

EP 0 836 835 A2

## Description

The present invention relates to a implant fixation system and locking mechanism. More particularly, the present invention provides a locking mechanism, which can be multi-planar or fixed, for securing a rod to an implant.

Stabilization of the spine for various conditions, including degenerative disc disease, scoliosis, spondylolithises and spinal stenosis often require attaching implants to the spine and then securing the implants to spinal rods. Such spinal fixation devices can immobilize the vertebrae and can alter the alignment of the spine over a large number of vertebrae by means of connecting at least one elongate rod to the sequence of selected vertebrae. Such rods can span a large number of vertebrae, such as three or four. However, the spine anatomy rarely allows for three or more implants to be directly in line. In order to allow for this irregularity, the rod must be contoured to the coronal plane. With anatomical curvature in the saggital plane found in the lumbar spine, the rod has to be contoured in both planes, requiring considerable effort and surgical time.

For example, the U.S. Patents 5,554,157, issued September 10, 1996, 5,549,608 issued August 27, 1996, and 5,586,984 issued December 24, 1996, all to Errico et al. disclose polyaxial locking screw and coupling element devices for use with rod fixation apparatus. The '157 patent discloses a coupling element including an interior axial passage having an interior surface which is inwardly curvate at the lower portion thereof such that it comprises a socket for polyaxially retaining a spherical head of a screw. The coupling element further includes a pair of vertically oriented opposing channels extending down from the top of the coupling element which define therebetween a rod receiving seat. The channel further provides the walls of the upper portion to a pair of upwardly extending members, each including an exterior threading disposed on the upper most portion thereof for receiving a locking nut. During the implantation of the assembly, the locking nut seats against the top of the rod which in turn seats on top of the screw head. The nut causes the rod to be locked between the nut and screw and the screw to be locked in the socket.

The '608 patent discloses a modification wherein a locking ring is disposed about the exterior of the lower portion of the coupling element and provides an inward force on an outwardly tapered portion upon downward translation thereof causing the interior chamber to crush lock a screw head therein to eliminate the polyaxial nature of the screw element coupling.

The '984 patent discloses a polyaxial orthopedic device including a cutter element having a tapered lower portion including a slotted interior chamber in which a curvated head of a screw is initially polyaxialed disposed. The coupling element includes a recessed for receiving a rod of the implant apparatus. A locking ring is disposed about the lower portion of the coupling element and provides an inward force on the outwardly tapered portion upon downward translation thereof. The vertical slots are caused to close and crush and thereby locking the screw head within the inter chamber thereof.

In the prior art embodiments, the locking mechanism locks both the rod and screw head simultaneously. No prior art patent allows for the spherical head of the screw to be locked at a desired angle prior to rod insertion. Likewise the only surface locking the rod in place is the surface between either the seat and a locking nut or the rod entrapped between a locking ring and the seat.

It would be desirable to increase the area of contact of the locking mechanism about the rod as this is a high stress site secured only by a friction fit. It would also be desirable to lock the screw head in place prior to fixation of the rod.

In accordance with the present invention, there is provided a spinal implant fixation assembly including bone fixation means for fixation to a bone and rod receiving means operatively connected to the bone fixation means. The rod receiving means includes a first seat having an inner wall for seating a portion of a rod therein. The assembly further provides locking means engaging the rod receiving means for forcing the inner wall to contour around and engage the rod seated therein and for locking and fixing the rod relative to the inner housing.

The present invention further provides a method for locking a rod to a bone by the steps of fixing a rod seating member to a bone and then seating a portion of a rod within a substantially U-shaped seat of the seating member. The rod is locked within the U-shaped seat while engaging in contouring at least a portion of the U-shaped seat about the rod.

The present invention further provides a spinal fixation assembly including screw head receiving means for retaining a head of a screw therein. The screw head receiving means is moveable within the assembly between a locked position entrapping the screw head and an unlocked position wherein the screw head enters or escapes.

A method is further provided for retaining a screw head in a spinal fixation assembly by inserting a screw head into an expanded pocket of an insert contained within a first portion of an internal portion of a body member wherein the internal portion includes the first portion which is radially outwardly recessed relative to a second portion and then moving the insert into the second portion which compresses the pocket of the insert into a contracted condition to fixedly engage the screw head within the pocket.

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Figure 1 is a side view partially in cross section of a first embodiment of the present invention;
Figure 2 is a side view of a second embodiment of the present invention;
Figure 3 is a side exploded view of a third embodiment of the present invention;
Figure 4 is a cross sectional side view of the third embodiment of the present invention as assembled;
Figure 5 is a cross scctional view of a further embodiment of the present invention;
Figure 6 is a cross sectional view of the forth embodiment of the present invention and a screw member disposed adjacent the assembly;
Figure 7 shows the screw member inserted into the pocket of the forth embodiment of the present invention;
Figure 8 shows the screw member and a rod member locked within the assembly, the assembly being shown in cross section;
Figure 9 shows a side view, and cross section of the insert member;
Figure 10 shows a cross sectional view of the body portion of the forth embodiment of the present invention;
Figure 11 shows a cross sectional view of the assembly having straight rod disposed therein;
Figure 12 shows a cross section of the assembly having a curved rod disposed therein;
Figure 13 is side view of the insert member of the forth embodiment of the present invention;
Figure 14 shows a side view of a second embodiment of the insert member;
Figure 15 shows a cross sectional view of a second embodiment of the body portion of the forth embodiment;
Figure 16 is a side view of a third embodiment of the insert;
Figure 17 is a side view of a forth embodiment of the insert combining the embodiment of the insert combining the embodiment shown in Figures 14 and 16; and
Figure 18 is a cross sectional view of the third embodiment of the body portion.

A spinal implant fixation assembly constructed in accordance with the present invention is generally shown at 10 in Figure 1. Similar structures amongst the several embodiments are shown by primed numbers in the various Figures.

More specifically, referring to the first embodiment of the present invention generally shown at 10 in Figure 1, the assembly 10 includes a bone fixation element generally shown at 12 for fixation of the assembly 10 to a bone. A rod receiving mechanism is generally shown at 14 and is operatively connected to the bone fixation element 12. The rod receiving mechanism 14 includes a seat 16 having an inner wall 18 for seating a portion of a rod 20 therein. A locking mechanism generally shown at 22 engages the rod receiving mechanism 14 for forcing the inner wall 18 to contour around and engage the rod 20 seated therein and for locking and fixing the rod 20 relative to the assembly 10. In this manner, as the locking mechanism 22 forces the inner wall 18 to contour around and engage the rod 20 seated therein, there is increased surface to surface contact and therefore increased frictional engagement between the seat 16 and rod 20 thereby providing a more effective frictional contact. That is, the inner wall 18 of the seat 16 is compressed against the rod 20. The locking mechanism 22 is also seated against the rod 20. However, unlike prior art assemblies discussed above, the surface area engaging against the rod 20 is vastly increased over the prior art which increases the assembly to rod holding power.

More specifically, the rod receiving mechanism 14 includes a tapered outer surface 24. As shown in the several embodiments, this outer surface 24 can be threaded. However, other means for securing the locking mechanism 22 can be used to achieve the same results. Preferably, the locking mechanism 22 is in the form of a nut member 26 having an inner surface 28, which can be threaded for use with the threaded outer surface 24 of the rod receiving mechanism 14, for being forced over and engaging the outer surface 24 and inwardly deflecting the rod receiving mechanism 14 about the seat portion 16 as the locking member 26 further engages the tapered outer surface 14.

Referring more specifically to the rod receiving mechanism 14, it includes a body portion 30 having two arms 32,34 extending therefrom and being substantially parallel relative to each other. The two arms 32,34 and the body portion 30 form a U-shaped inner surface defining the seat portion 16 thereof. Also, the arms 32,34 have the tapered threaded surface 24 about the outer surface thereof. Thus, as the locking mechanism 22 in the form of the nut member 26 is threaded over the tapered outer surface 24 of the arms 32,34, the nut member 26 compresses the arms 32,34 against a rod member 20 disposed within the seat 16. As stated above, this provides a vastly increased surface area engagement between the seating surface 16, inner walls 18 and rod member 20. The arms 32,34 provide for flexibility, yet are sufficiently rigid to maintain structural integrity.

The tapered threaded portion 24 in combination with the nut member 26 provide a self-locking mechanism for securing the rod 20 thereto. By self-locking, it is meant that mere threading of the nut member 26 on the tapered surface 24 locks the nut member 26 in place. This locking mechanism is vibration resistant and has not been previously used in spinal implants. In combination with the other aspects of the present invention, the self-locking mechanism provides convenience of use and secure locking of the system along with flexibility of attachment of the rod and implant.

In the first embodiment shown in Figure 1, the bone fixation mechanism 12 is shown as a screw portion 36

extending integrally from the body portion 30. The body portion 30 includes a longitudinal axis. The bone fixation element 12, whether it is a screw portion as shown in Figure 1 at 36 or a hook portion 38 as shown in Figure 2, can either 1) lie along the axis so as to define a substantially linear element or 2) be angled relative to the longitudinal axis of the body portion 30. In this manner, the device can be adapted to various angulations between the bone connection surface and the rod 20. These embodiments of the invention provide either a thread or hook portion 36,38, respectively, having the upper tapered threaded portion about the U-shaped seat 16. Variability of angulation is eliminated as each unit would be a solid fix piece. But the assemblies can be individually made in various angulations. Such assemblies provide solid fixation of implants to the rod 20 where angulation is either not required or where known angulation may be repeatedly needed.

As stated above, the bone fixation element 12 can take on various shapes and sizes known in the art. The element 12 can have various configurations as a screw 36 and various thread designs. Also, as shown in Figure 2, the hook portion 38 can be manufactured and used in a variety of hook sizes. Other shapes and sizes well known in the art.can also be used.

The assembly is preferably made from machined titanium or alloy, but can be alternatively made from other types of cast or molded materials well known in the art.

A second alternative embodiment of the present invention is shown in Figures 3 and 4. As stated above, double primed numbers are used to indicate like structure between the several embodiments.

Referring specifically to Figures 3 and 4, the bone fixation element 12" is shown as an independent screw member. The element 12" includes a head portion 40 having a substantially spherical outer surface 42. The rod receiving mechanism 14" is shown as a single integral unit including the first seat 16" for receiving the rod member 20" as discussed above between the arms 32" and 34" and a second seating surface 44 having a substantially spherical shape for seating the head portion 40 of element 12" therein.

Referring more specifically to the rod receiving member 14", it consists of a substantially tubular body including the pair of spaced substantially parallel arms 32",34" extending therefrom and forming the substantially U-shaped seat 16" as discussed above. The tubular body further includes a socket portion defining the second seat 44 which includes outwardly flaring flanges 46, as best shown in Figure 3. The outwardly flaring flanges 46 have distal ends which flare radially outwardly relative to a central axis of the rod receiving member 14. The outer surfaces 50 define the outer surface of the second seat 44.

The head portion 40 and/or the seat 44 can have a textured surface for better gripping of the spherical outer surface 42. The textural surface can take on various forms, such as ripples abrasions or the like, which increase the effective surface to surface contact and provide micro or macro grips against the outer surface 42.

The locking mechanism 22" of this embodiment includes the nut member 26" and a tubular sleeve member generally shown at 52. Although the nut member 26" and sleeve member 52 are shown as separate elements, the present invention could be practiced where the nut member 26" includes a skirt portion integrally extending therefrom. In either embodiment, the sleeve 52 locks and fixes the head portion 40 of the screw element 12" within the seat 44 prior to the nut member 26" locking and fixing the rod 20" within the seat 16". The sleeve member 52 includes an inner surface 54 which, upon being disposed over and about the outer surface 50 of the flanges 46, engages and inwardly deflects the distally outwardly tapering surfaces thereof to engage the socket portion of the seat 44 with the head portion 40 of the screw member 12". This can be accomplished prior to the connection of member 14" with the rod 20" and its locking in place by the nut member 26".

Referring more specifically to the sleeve member 52, it includes curved recessed portions 54 for seating of the rod member 20" therein in the assembled configuration as shown in Figure 4. The sleeve 52 also includes a skirt portion 56 which is disposed about the flanges 46 in the assembled position, as shown in Figure 4. In the embodiment shown in Figures 3 and 4, the element 30" includes the tapered threaded outer surface 24" which can be engaged by the threaded inner surface 28" of the nut member 26". As the nut member 26" is threaded over the outer tapered surface 24", it not only inwardly deflects the arms 32",34" to engage the rod member 20" but also forces the skirt portion 56 of the sleeve member 52 over the outwardly flared flanges 46 so as to force the inner surface of the seat 44 to frictionally engage and hold in place in a fixed manner the head portion 40 of the screw element 12". The screw element 12" is then locked securely at whatever angle the components are in. This locking is independent of the locking of the rod 20" in place.

This locking of thc screw element can occur in two ways. The outer sleeve 52 can be pushed down with an instrument without the rod being in place or pushed down as the nut 26" is tightened over the rod 20". This gives the surgeon the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20" to the assembly 10" or, alternatively, locking the screw element 12" and rod 20" interfaces simultaneously when correction is not required.

As stated above. the head portion 40 is shown to be substantially spherical in shape. The seat 44 is a socket portion which is also substantially spherical for seating and engaging the head portion 40 therein. This allows for easy angular adjustment between the two components. Alternatively, the head portion 40 of the screw element 12" can take on various other shapes, such as a square shape, which may not allow for similar

angulation but would allow for similar connection between the head portion 40 and the seat 44 in accordance with the present invention.

In the embodiment as shown wherein the head portion 40 is of a spherical shape for mating with the spherically shaped female seating portion 44, the configuration allows for up to 25° or more of angulation in all directions relative to the shaft portion 58 of the screw element 12". Thus, the present invention provides a multiplanar locking mechanism that allows for angulation in all planes. It also provides a locking mechanism that allows the mechanism to be locked at any angle prior to rod insertion. Further results of the above is that the invention provides a multi-planar locking mechanism that reduces intraoperative rod contouring provides flexibility.

With more specific regard to the locking mechanism, the sleeve ring 52 includes an edge surface 58. The nut member 26" includes an abutment surface 60 for abutting against the edge 58 as the nut member 26" is threaded onto the tapered threaded portion 24" to force the ring member 52 over the outer surface of the flanges 50.

In operation, the screw element 12" is fixed onto a bone, the head portion 40 extending from the bone surface. The rod seating member 14" is then disposed over the head portion 40 of the screw element 12" by insertion of the head portion 40 into the seat 44. This is a snapping operation but allows for angular adjustment of the tubular member 14" relative to the longitudinal axis of the screw element 12". The ring 52 is then disposed over the member 14" and an instrument is used to force the ring member 52 over the flanges 50 so as to lock the head portion 40 within the seat 44 thereby fixing the angulation between the two elements. The rod 20" is then seated within seat 16" of the member 14" as well as within the groove 54 of the ring 52. Finally, the nut member 26" is threaded over the tapered outer surface 24" of the arms 32",34" thereby fixing the rod 20" in frictional engagement within the seat 16" and against the nut member 26". Alternatively, as discussed above, the nut member 26" can be used to force the sleeve member 52 in place so as to lock the head 40 and screw member 12" relative to the element 14".

Utilizing the embodiment of the present invention as shown in Figures 1 and 2, the process is exactly the same with regard to locking the rod member 20 in place once the screw or hook portions 36,38, respectively, are connected to the known.

In view of the above, the present invention provides a method for locking a rod 20, 20" to a bone by the general steps of first fixing a rod seating member 14,14',14" to a bone and then seating a portion of the rod 20,20" within a substantially U-shaped seat 16,16" of the seating member 14,14',14". The rod 20,20" is locked within the U-shaped seat 16,16" while engaging and contouring at least a portion of the U-shaped seat 16,16" about the rod 20,20". As shown in Figures 3 and 4, this method can be more specifically defined by the steps of fixing the bone fixation member 12" to a bone and then locking and fixing the rod seating member 14" to the head portion 40 of the bone fixation member 12" and then locking the rod 20" within the U-shaped seat 16". The fixing step is accomplished by forcing the ring 52 over the outwardly flared portions 46 of the seat portion 44 to lock and fix the head portion 40 of the bone fixation element 12" therein. Finally, the locking of the rod is accomplished by locking the rod 20" within the U-shaped seat 16" by engaging the inner threaded surface 28" of the nut member 26" over the tapered outer threaded surface 24" of the U-shaped seat 16" to force the ring 52 over the outer surface 50 of the seat portion 44 to lock and fix the head portion 40 of the bone fixation element 12" therein while simultaneously deforming the inner surface of the U-shaped seat 16" about the rod 20" seated therein.

A further embodiment of the present invention is shown in Figures 5-8. This embodiment of the invention includes the bone fixation element generally shown at 12"", this embodiment being characterized by including a screw head receiving insert generally shown at 70 which is moveable within the assembly 10"" between a locked position as shown in Figures 7 and 8 entrapping the screw head 40"" therein and an unlocked position wherein the screw head 40"" enters or escapes, as shown in Figures 5 and 6. That is, this embodiment of the invention includes a single unit capable of receiving a screw head 40"" therein and then allowing for polyaxial adjustment of the screw head relative to the assembly and then locking of the screw head within the assembly without requirement of additional elements to the assembly. This embodiment of the invention drastically reduces surgical time in spinal surgery and simplifies the elements needed for implementing the bone fixation. Such a system is particularly useful when the rod 20"" in not lined up with the screw 12"".

More specifically, the assembly 10"" includes a body 30"" including an internal portion 72"". The internal portion 12"" generally includes a first portion 74 which is radially outwardly recessed relative to a second internal portion 76. The internal portion 74 can be effectively recessed or actually recessed. The first portion could have a greater diameter than the second portion or the second portion could be formed by flanges that extend radially internally from an inner surface of the second portion thereby effectively defining the end of each flange as the radially inwardly extending surface.

The screw head receiving means 70 consists of a insert member 70 including a seat 44"" for seating the screw head 40"" therein. The insert 70 is moveable within the internal portion 72 between the locked and unlocked position as discussed below.

Figure 9 shows an enlarged cross-sectional view of the insert 70 made in accordance with the present invention. The seat 44"" more particularly includes a base portion 78 and a plurality of flexible arms 80 extending therefrom combining with the base portion 78 to form a

pocket. The arms 80 define flexible walls of the pocket extending from the base portion 78.

As least one of the arms 80 includes a hinged portion 82 allowing for outward deflection of the arm 80. The hinged portion, as shown in Figure 9, can be a recess cut into the base portion 78 adjacent the arm 80 to allow for increase outward flexibility of the arm 80 which includes the hinged portion 82. This allows for increased ease of insertion of the screw head 40"" into the pocket.

Figures 5-8 sequentially show the method of using the present invention for fixing a polyaxial screw 12"" therein. The screw itself 12"" is inserted into the bone by itself. This provides excellent visualization of screw placement since the larger body/insert assembly 10"" is pushed on the screw head after screw insertion into the bone.

As shown in Figure 5, the insert 70 is sufficiently collapsible to be snapped into the internal portion 72 of the body element 34"". This is accomplished by compressing the insert 70 and releasing it inside the internal portion 72. The assembly itself can be made from any durable material, such as carbon composites, nitinol, stainless steel, composite materials, plastics and plastic compositions or even resorbable materials. Preferably, titanium is used to minimize artifacts from x-rays and other diagnostic imaging systems. The combined assembly effectively provides the equivalent of a one piece assembly which is a significant improvement over prior art two piece assemblies or multiple piece assemblies necessary for only securing a screw head within a fixation device.

When the insert 7 is disposed within the first portion 74 of the internal portion 72, there is internal space to allow for slight expansion of the insert 70 therein. When the screw head 40"" is disposed into the internal portion 72, the screw head 40"" will effectively force the insert 70 into the first portion 74 thereby ensuring the ability of the pocket to expand sufficiently to allow insertion of the screw head 40"" into the pocket. Once the screw head 40"" is fully inserted into the pocket, the insert 70 snaps onto the screw head 40"". In this condition, polyaxial movement can be achieved.

Locking can be achieved in two manners. The body 30"" can be pulled up relative to the screw 12"" with an instrument (not shown) without the rod 20"" being in placed or pulled by the nut 26"" as the nut 26"" is tightened over the rod 20"". This provides the surgeon with the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20"" to the assembly 10"" or locking the screw 12"" and rod 20"" interfaces simultaneously when correction is not required.

As shown in Figure 8, the U-shaped inner surface defining the seat portion 16"" extends into the internal portion 72. Upon seating of the rod 20"", the inserted portion of the rod 20"", contacts a portion of the surface of the base portion 80 of the insert 70 for final seating of the insert 70 within the second portion 76 of the internal portion 72. As best shown in Figure 10, which shows a cross section of the body portion 30"", the second portion 76 includes a radially inwardly tapering surface. Thus, as the insert 70 is drawn into the second portion 76, the outer surface of the arms 80 of the insert 70 are progressively compressed about the screw head 40"" thereby effectively engaging and locking the screw head 40"" in position relative to the body portion 30"". Upon final locking of the rod 20"" within the assembly 10"", as described above, complete fixation is achieved.

Also significant with regard to this embodiment is the fact that the nut 26"", which includes a tapered treaded internal surface as discussed above, compresses the tapered threaded portion 14"" of the assembly 10"" against the rod 20"". The nut 26"" will also seat against the rod 20"", but the surface area engaging the rod 20"" will be vastly increased over the prior art, which increases the assembly to rod holding power. In fact, the nut against the rod is only a secondary locking means. The force of the portions 14"" against the rod 20"" is the primary locking mechanism. In other words, the rod 20"" is engaged by the nut 26"", the body portion 30"", and the insert 70. Effective engagement of the insert 70 is significant as demonstrated in Figures 11 and 12.

Figure 11 shows a cross section of the assembly wherein a straight rod 20 is retained within the assembly. With such a straight rod 20, the rod 20 will push the insert 70 down until the rod 20 fits within the U-shaped channel of the body 30"". It is ideal for the rod 20 to contact the edges of the body 30"" inside the U-shaped channel for maximum rod gripping strength. When the rod 20 is contoured, as shown in Figure 12, the insert 70 of the present embodiment can self-adjust and be pushed downward further then the edges of the body 30"" within the U-shaped cut-out to maximize rod contact. Such self adjustment is not at all found in the prior art since such U-shaped cut-outs in a body portion are fixed machine surfaces.

Figures 13-18 shown various permutations of the insert and body portions of the present invention. Figure 13 shows an insert 70 including arms 80 having smooth outside surfaces. This is an embodiment which is shown in the previously discussed figures. In Figure 14, the insert 70" includes arms 80" having an stepped outer surface 82. Such a step outer surface provides a stop for engaging the inner surface of the internal portion 72 to prevent the insert 70" from moving beyond the desired engagement location. Figure 16 shows an insert 70" including a radially inwardly tappered outer surface portion 84 for progressive engagement with the second portion 72. Figure 17 shows a further embodiment of the insert 70" combining the inward tappered surface 84" with the step 82".

Figure 15 shows a body portion 30"" wherein the second portion 76 includes a radially inwardly extending lip 86 at the peripheral edge thereof. Figure 18 shows a chamfered surface 88 a the peripheral edge of the second portion 76. both the lip 86 or the chamfered portion

88 provide further stops to ensure that once the insert member 70 is disposed within the internal portion 72, the insert 70 does not inadvertently exit therefrom.

The components for the assembly can be manufactured according to the following techniques, but every manufacturer has their own variations.

The body is made by first blanking the outer shape from round bar stock. By holding on the threaded end, or an extension to the threaded end (extra bar material), a hole is made into the opposite end. This hole is undersize relative to the taper to allow the taper to be but with a single tool. While the part turns in a lathe, a boring bar having a small cutting tip is introduced into the hole and the taper and recess cut. The threads are then cut, any extension cut off, and the slot either milled or cut be more EDM.

The insert is made by cutting the outside cylindrical shape with an extension to hold on in a lathe. A hole is drilled into one end and a boring bar with a small cutting tip used to enter the hole and cut the spherical seat. The outer slots and hinge details are cut by either a slitting saw or a wire EDM.

Another possibility for the insert is to have a U cut or indentation in the top of it for seating of the rod. This is not preferable, since orientation of the insert would then be necessary, but possible.

Another addition to the body at the threaded portion is to add a recess in the side of the arms of the U on the inside for a rod to fit within. This would act as a guide for seating the nut with an instrument, as it would align the nut relative to the threads.

In combination, this last described embodiment provides a novel fixation assembly which can be either combined with the novel rod retaining features described above or with other types of rod retaining features resulting in a simple effective and efficient means for fixing a screw member to a rod.

In accordance with this method, the locking mechanism is locked to the spherical head 40 of the bone fixation element 12" at a desired angle prior to rod insertion or locked simultaneously by tightening of the nut member 26". This locking method and the mechanism used therewith is fully reversible and top loading.

The invention has been described in an illustrative manner, and it is to be understood that the terminology which has been used is intended to be in the nature of words of description rather than of limitation.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically describe.

**Claims**

1. A spinal implant fixation assembly (10) comprising:

bone fixation means (12) for fixation of the assembly (10) to a support;
rod receiving means (14) operatively connected to said bone fixation means (12) and including a first seat (16) having an inner wall (18) for seating a portion of a rod (20) therein; and
locking means (22) engaging said rod receiving means (14) for forcing said inner wall (18) to contour around and engage the rod (20) seated therein and for locking and fixing the rod (20) relative to said assembly (10).

2. An assembly according to claim 1, wherein said rod receiving means (14) includes a tapered outer surface (preferably, a tapered threaded surface) (24), said locking means (22) including an inner surface (preferably an inner threaded surface) for being forced over and engaging said outer tapered surface (24) and inwardly deflecting said rod receiving means (14) about said first seat (16) as said locking means (22) further engages said tapered outer surface; and/or

wherein said rod receiving means (14) includes a body portion (30) having two arms (32,34) extending therefrom and being substantially parallel relative to each other, said two arms (32,34) and body portion (30) forming a U-shaped inner surface defining said first seat, said arms (32,34) including a tapered threaded surface (24).

3. An assembly according to claim 1 or claim 2, wherein said fixation means comprises means for fixing said assembly (10) to a bone; preferably wherein said body portion (30) includes said fixation means (12) extending therefrom at a predetermined angle relative to said inner wall (18) defining said first seat (16); and/or

wherein said fixation means (12) includes a hook portion (38) or a screw portion (12) extending from, and integral with, said body portion (30').

4. An assembly according to claim 3, wherein said bone fixation means (12") includes a head portion (40), said rod receiving means (14") including a second seat (44) for seating said head portion (40) therein (and preferably gripping means for gripping said head portion (40) within said second seat (44), said second seat (44) including an outer surface (50) thereabouts, said locking means (22") including a skirt engaging and radially inwardly deflecting said outer surface of said second seat portion (42) for first locking and fixing said head portion (40) within said second seat (44) prior to said locking means (22") locking and fixing the rod (20") with the

first seat (16").

5. An assembly according to claim 4, wherein said rod receiving means (14") comprises a substantially tubular body including a pair of spaced, substantially parallel arms (32",34") extending therefrom and forming a substantially U-shaped seat defining said first seat (16"), said tubular body further including a socket portion including outwardly flaring flanges (46) having distal end portions flaring radially outwardly tapering surfaces (50) relative to a central axis of said rod receiving means defining said outer surface (50) of said second seat (44), said skirt portion (52) engaging and inwardly deflecting said distally outwardly tapering surfaces to engage said socket portion with said head portion (40).

6. An assembly according to claim 5, wherein said locking means includes a ring member (52) defining said skirt portion, said tapered outer surface (24") of said rod receiving means (12") being a tapered threaded surface, said locking means (22") further including a nut member (26") including an inner threaded surface (28") for engaging and inwardly deflecting said tapered threaded surface (24"); and/or wherein said head portion (40) is substantially spherical, said socket portion being substantially spherical for seating and engaging said head portion (40) therein.

7. An assembly according to claim 6, wherein said ring (52) includes an edge surface (58), said nut member (26") including an abutment surface (60)for abutting against said edge surface (58) as said nut member (26") is threaded onto said tapered threaded portion (24") to force said ring member (52) over said outer surface of said socket portion.

8. A spinal implant fixation assembly (10) comprising:

bone fixation means (12) for fixation for the assembly (10) to a support;
rod receiving means (14) operatively connected to said bone fixation means (12) and including a first seat (16) for seating a portion of a rod therein; and
self-locking means (22) disposed about said rod receiving means (14) for securing and self-locking the rod (20) seated within said first seat (16) and fixing the rod (20) relative to said assembly (10).

9. An assembly according to claim 8, wherein said self-locking means including an outer tapered surface (24) (preferably a tapered threaded surface) of said rod receiving means (14) and a nut member (26) having an inner surface (preferably an inner threaded surface) for being forced over and engaging said outer tapered surface (24).

10. A spinal fixation assembly (10"") comprising screw head receiving means (70) for retaining a head (40"") of a screw (12"") therein, said screw head receiving means (70) being movable within said assembly (10"") between a locked position entrapping the screw head (10"") and an unlocked position wherein the screw head (10"") enters or escapes.

11. An assembly according to claim 10, wherein said assembly (10"") includes a body (30"") including an internal portion (72), said screw head receiving means (70) including an insert member including a seat (44"") for seating the screw head (40"") therein, said insert being movable within said internal portion (72) between said locked and unlocked positions, said seat (44"") preferably including a base portion (78) and a plurality of flexible arms (80) extending therefrom combining with said base portion (78) to form a pocket, said arms (80) defining flexible walls of said pocket extending from said base portion (78);

at least one of said arms (80) preferably including a hinge portion (82) for allowing outward deflection thereof, said arms of said insert member preferably including an outer surface including engagement means for engaging an inner surface of said internal portion; and/or
said arms preferably having an outer surface tapering inwardly away from said base portion.

12. An assembly according to claim 11, wherein said internal portion includes stop means for engaging an outer surface of said arms (80) to retain said insert member within said internal portion; and/or

wherein said body portion (30"") includes a rod retaining means for retaining a rod therein, said internal portion (72) including a fist portion adjacent to said rod retaining means and a second portion extending from said first portion said first portion having an inner surface recessed radially outwardly relative to said second portion, said second portion preferably including a radially inwardly extending lip at an end thereof most distal relative to said first portion.

13. An assembly according to claim 12, wherein said second portion includes an end edge most distal relative to said first portion, said end edge being chamfered radially thereabout; and/or

wherein said internal portion includes an annular shoulder between said first and second portions, said outer surface of said arms including a step defining said engagement means for en-

gaging said shoulder to prevent said insert from moving beyond a desired engagement location, said arms preferably having an outer surface tapering inwardly away from said step.

14. An assembly according to claim 11, wherein said body includes a neck portion, said rod retaining means including two opposed U-shaped seats extending into said neck portion, said U-shaped seat having a bottom portion thereof extending into said internal portion such that a rod seated in said U-shaped seat abuts against said insert member disposed within said first portion and frees said insert member into said second portion, said outer walls of said arms engaging and being forced radially inwardly by said second portion to collapse and engage a screw head disposed within said pocket.

15. An insert for retaining a screw head in a spinal fixation assembly, said insert comprising:

a base portion and a plurality of flexible arms extending therefrom combining in with said base portion to form a pocket, said arms defining flexible walls of said pocket extending from said base.

16. A body member of a spinal fixation assembly comprising;

rod receiving means for receiving a portion of a rod member therein; and
an internal portion for movably retaining a screw head receiving insert therein.

17. A body member according to claim 16, wherein said internal

portion includes stop means for engaging an outer surface of the insert to retain the insert therein; and/or
wherein said body portion includes a rod retaining means for retaining a rod therein, said internal portion including a first portion adjacent to said rod retaining means and a second portion extending from said first portion, said first portion having an inner surface recessed radially outwardly relative to said second portion, preferably said second portion including a radially inwardly extending lip at an end thereof most distal relates to said first portion, or an end edge most distal relative to said first portion, which end edge is chamfered radially thereabout.

18. A spinal fixation assembly comprising:

a body member including an internal portion and an insert member including a screw head receiving pocket having an expanded condition to receive and release a screw head and a contracted condition for fixedly engaging a screw head therein, said internal portion movably containing said insert member between a first portion of said internal portion wherein said insert member is in said expanded condition and a second portion wherein said insert member is in said contracted condition, said first portion preferably being radially outwardly recessed relative to said second portion.

19. A method or retaining a screw head in a spinal fixation assembly by;

inserting a screw head into an expanded pocket of an insert contained within a first portion of an internal portion of a body member wherein the internal portion includes the first portion which is radially outwardly recessed relative to a second portion and;
moving the insert into the second portion, which comprises the pocket of the insert, into a contracted condition to fixedly engage the screw head within the pocket.

20. A method according to claim 19 including the further steps of disposing a portion of a rod member into a seat portion of the body member, abutting the disposed portion of the rod member against the insert member which is disposed in the first portion in the expanded condition and moving the insert into the second portion, the rod member locking the insert in the second portion, preferably wherein a non-straight portion of the rod is inserted into the seat portion and the insert member is further compressed into the first portion.

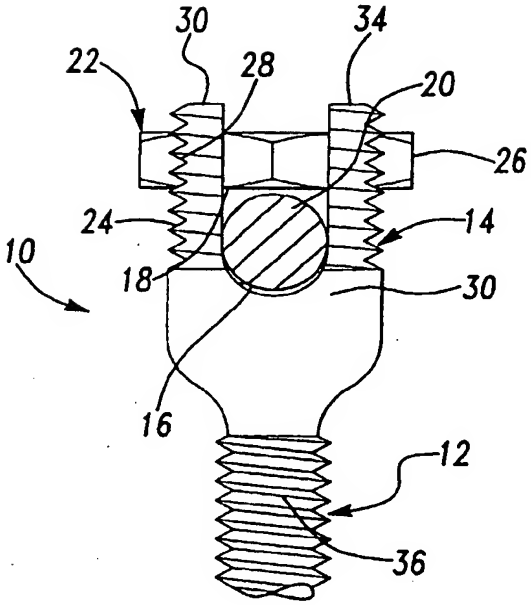
21. A method of fixing a rod within a spinal fixation assembly by;

disposing a portion of a rod member into a seat portion of a body member of the assembly; and
compressing the portion of the rod member against a compressible insert within the seat portion, the insert gripping said portion of the rod.

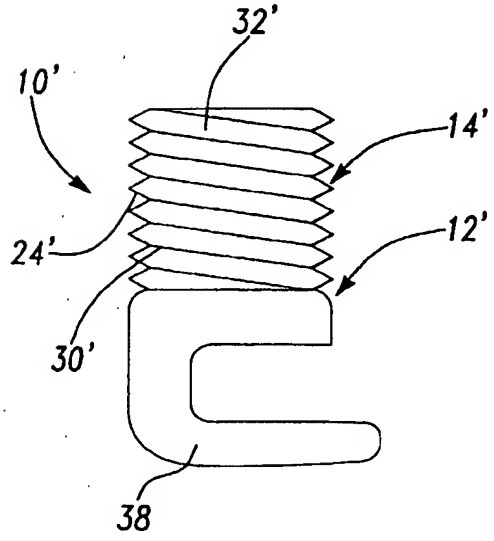
22. A method for locking a rod (20,20") to a bone by fixing a rod seating member (14,14'14") to a bone; seating a portion of a rod (20,20") within a substantially U-shaped seat (16,16") of the seating member (14,14'14"), and locking the rod (20,20") within the U-shaped seat (16,16") while engaging and contouring at least a portion of the U-shaped seat (16,16") about the rod (20,20").

23. A method according to claim 22, further including the steps of fixing a bone fixation member (12") to a bone; locking and fixing a rod seating member (14") to a head portion (40) of the bone fixation member (12"), and then locking the rod (20") within the U-shaped seat (16"), preferably wherein said locking and fixing step is further defined as forcing a ring member (52) over an outwardly flared portion (46) of a seat portion (44) to lock and fix the head portion (40) of the bone fixation member (12") therein.

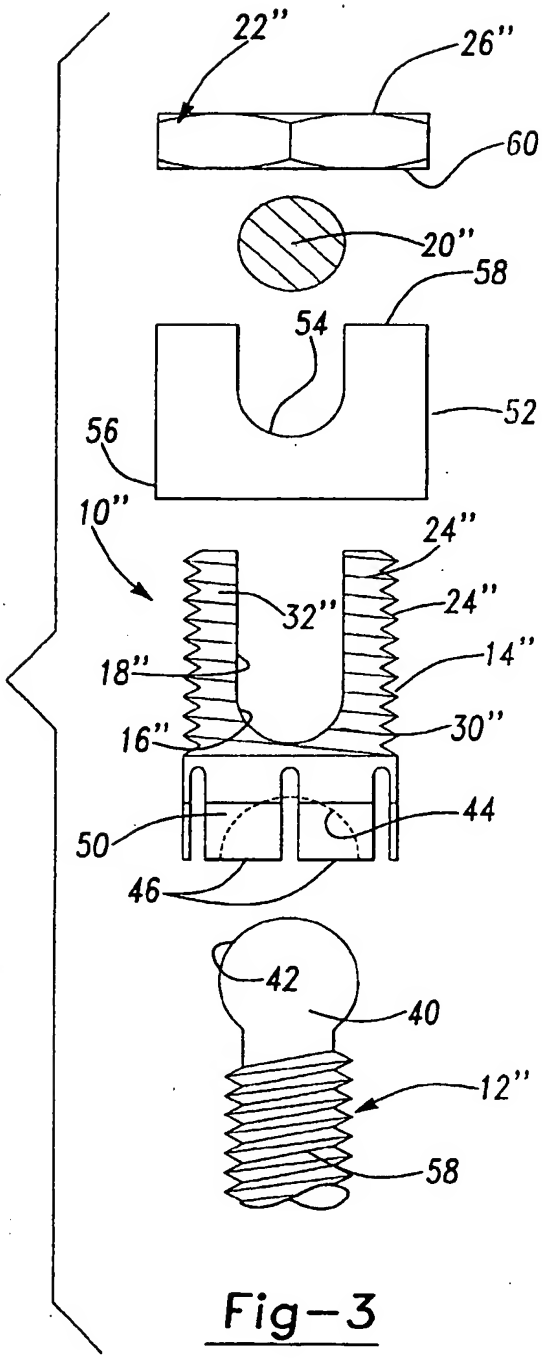
24. A method according to claim 23, wherein said step of the locking the rod (20") within the U-shaped seat (16") is further defined as enlarging an inner threaded surface (28") of a nut member (26") over a tapered outer threaded surface (24") of the U-shaped seat (16") to force the ring (52) over the outer surface (50) of the seat portion (44) to lock and fix the head portion (40) of the bone fixation member (12") therein while simultaneously deforming the inner surface of the U-shaped seat (16") about the rod (20") seated therein.



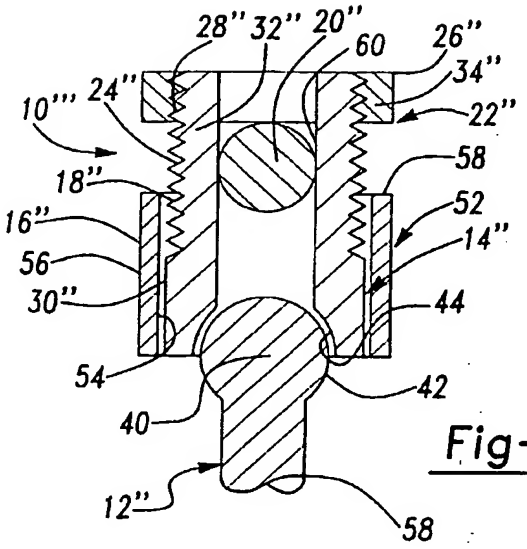

Fig–1



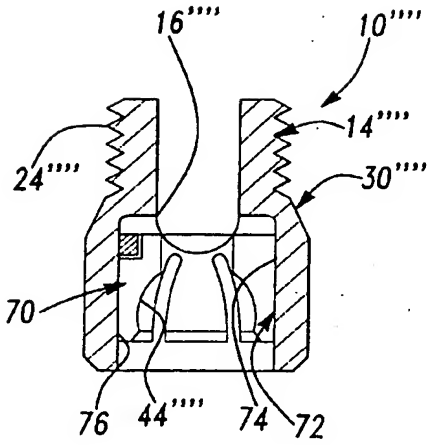

Fig–2



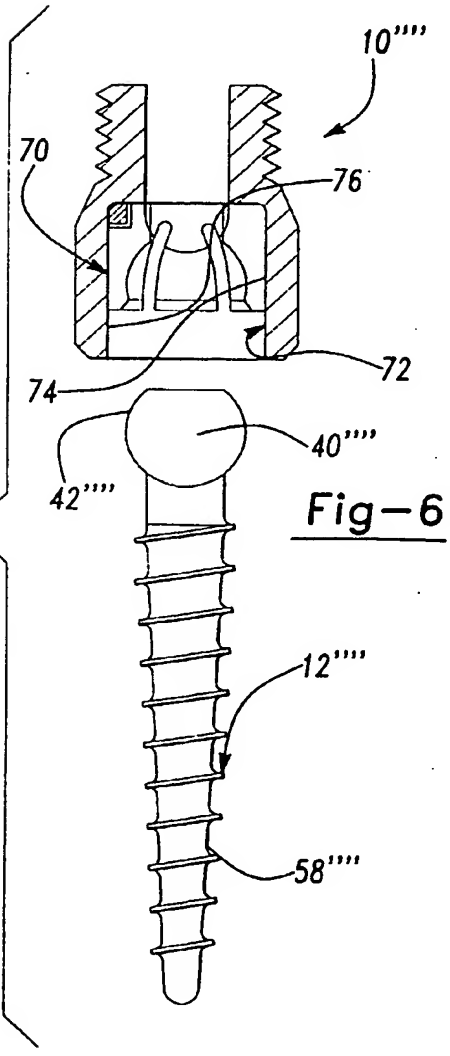

Fig–3



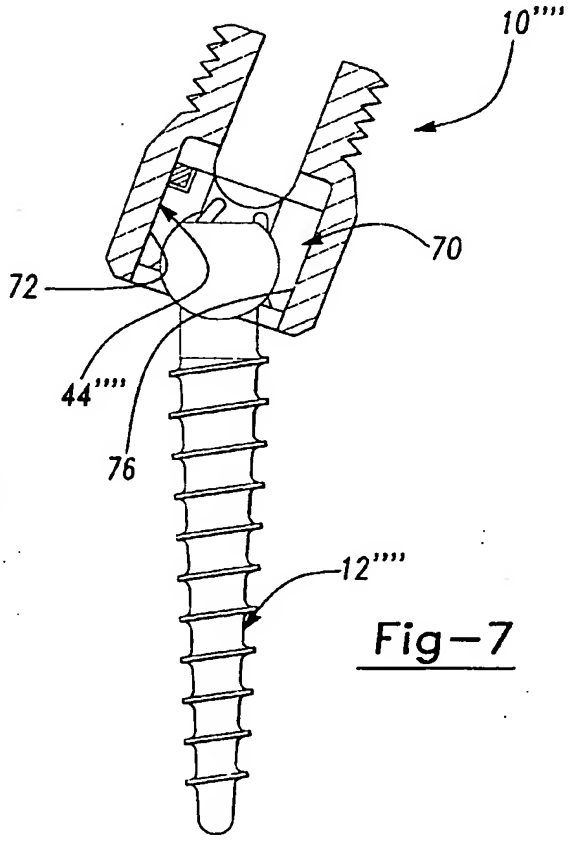

Fig–4




Fig–5




Fig–6




Fig–7

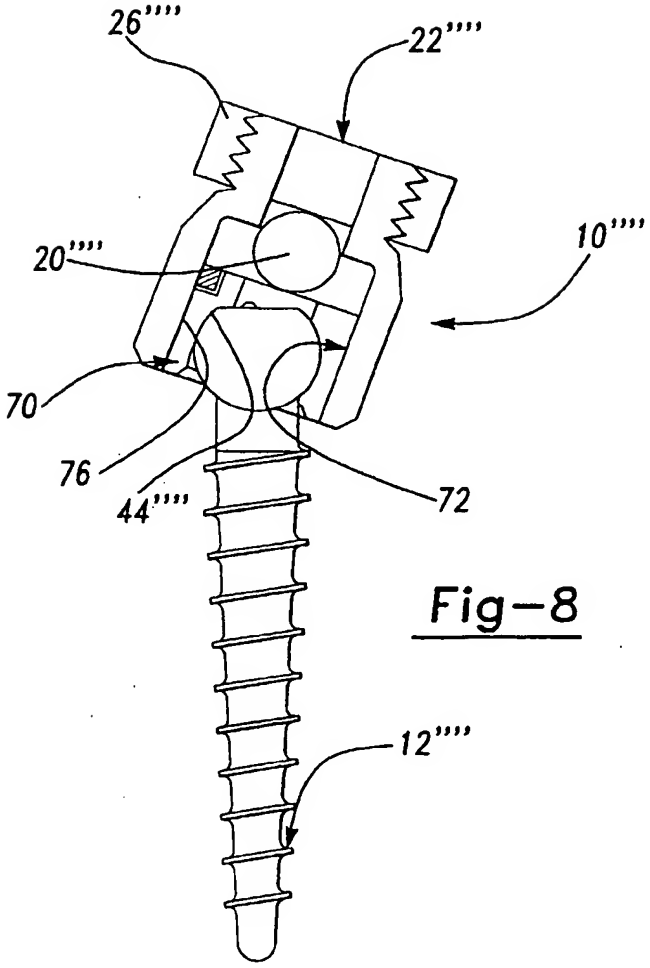



Fig-8

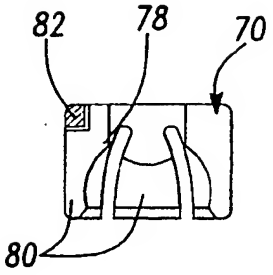



Fig-9

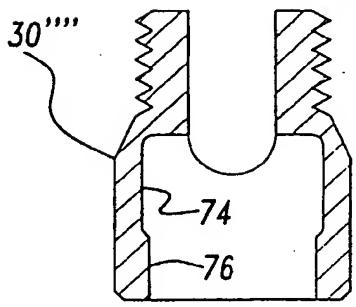



Fig-10

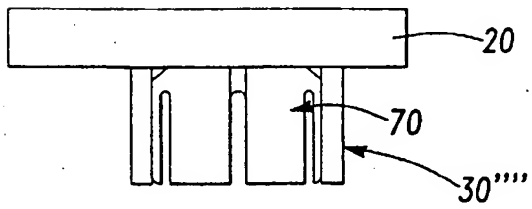



Fig-11

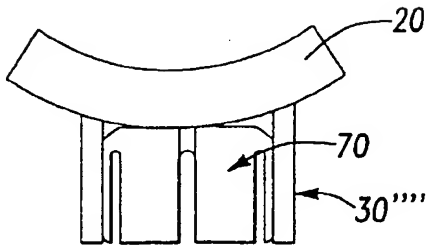



Fig-12

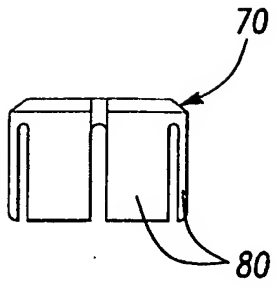



Fig-13

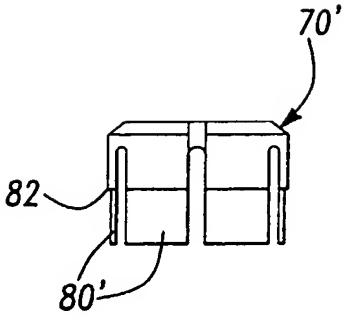



Fig-14

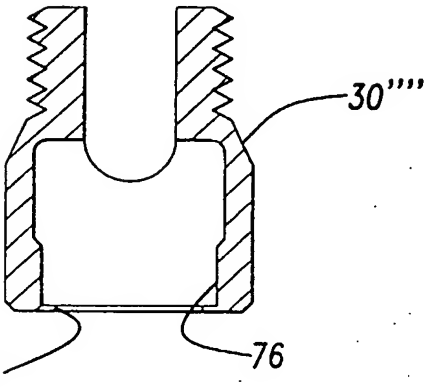



Fig-15

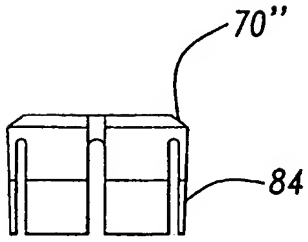



Fig-16

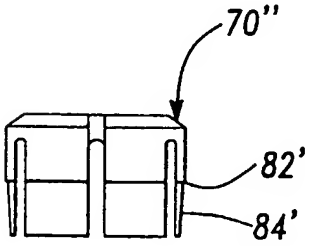



Fig-17

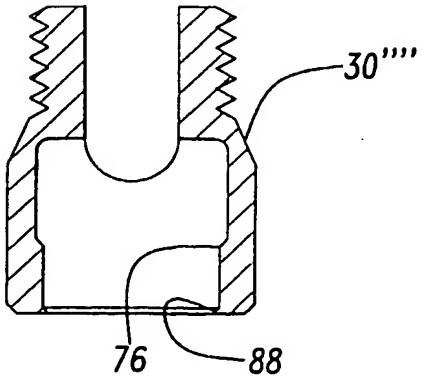



Fig-18

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 836 835 A3

# (12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
**01.07.1998 Bulletin 1998/27**

(43) Date of publication A2:
**22.04.1998 Bulletin 1998/17**

(21) Application number: **97308140.9**

(22) Date of filing: **14.10.1997**

(51) Int Cl.[6]: **A61B 17/70**

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE**
Designated Extension States:
**AL LT LV RO SI**

(30) Priority: **18.10.1996 US 734520**
**01.04.1997 US 831112**

(71) Applicant: **Spinal Innovations**
**Cordova, TN 38018 (US)**

(72) Inventor: **Richelsoph, MARC**
**Memphis,TN 38133 (US)**

(74) Representative: **Davies, Gregory Mark**
**Urquhart-Dykes & Lord**
**Alexandra House**
**1 Alexandra Road**
**Wales**
**Swansea, Wales SA1 5ED (GB)**

## (54) Spinal implant fixation

(57) A spinal implant fixation assembly includes a bone fixation member, such as a screw or hook for fixation to a bone. A rod receiving seat is operatively connected to the bone fixation element for seating a portion of a rod therein. A locking mechanism, in the form of a nut and locking ring engage the rod receiving seat for forcing an inner wall of the rod receiving seat to contour around and engage the rod seated therein and for locking and fixing the rod relative to the inner housing. In one embodiment, the locking ring secures a head portion of the bone fixation element within the assembly. A method is also provided for locking the rod to a bone by fixing a rod seating member to a bone and seating a portion of a rod within a substantially U-shaped seat of the seating member. The rod is then locked within the U-shaped seating member while engaging and contouring at least a portion of the U-shaped seat about the rod. The assembly further includes a screw head receiving insert for obtaining a head of screw therein. The insert is moveable within the assembly between a locked position entrapping the screw head and an unlocked position wherein the screw head enters or escapes.

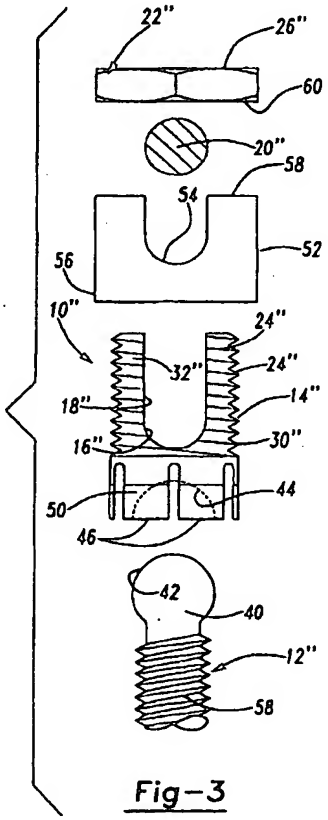



Fig-3

EP 0 836 835 A3

European Patent Office

# PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 97 30 8140

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int.Cl.6) |
|---|---|---|---|
| X,D | US 5 549 608 A (ERRICO ET AL.) 27 August 1996<br>* abstract; figures * | 1-3, 8-10,15, 16,18 | A61B17/70 |
| Y | | 4-7 | |
| Y,D | US 5 554 157 A (ERRICO ET AL.) 10 September 1996<br>* abstract; figures * | 4-7 | |
| X | DE 195 09 332 C (HARMS ET AL.) 14 August 1996<br>* the whole document * | 1-4,8-18 | |
| X | FR 2 682 280 A (LA BIOMECANIQUE INTEGREE (S.A.R.L.)) 16 April 1993<br>* abstract; figures * | 1-3,8,9 | |
| X | WO 91 01691 A (J.B.S. S.A.) 21 February 1991<br>* page 9, line 26 - page 10, line 7 *<br>* page 13, line 31-35; figures 1-7,11-14A * | 1-3,8,9 | |
| | -/-- | | TECHNICAL FIELDS SEARCHED (Int.Cl.6)<br>A61B |

## INCOMPLETE SEARCH

The Search Division considers that the present application, or some or all of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for the following claims:

Claims searched completely :

1-18

Claims searched incompletely :

Claims not searched :

19-24

Reason for the limitation of the search:

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| THE HAGUE | 7 May 1998 | Giménez Burgos, R |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

European Patent Office

**INCOMPLETE SEARCH**
**SHEET C**

Application Number
EP 97 30 8140

Claim(s) searched completely:
1-9

Claim(s) not searched:
19-24

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

European Patent Office

# PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 97 30 8140

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | CLASSIFICATION OF THE APPLICATION (Int.Cl.6) |
|---|---|---|---|
| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | |
| A | US 5 443 467 A (HARMS ET AL.) 22 August 1995<br>* abstract; figures *<br>--- | | |
| P,X, D | US 5 586 984 A (ERRICO ET AL.) 24 December 1996<br>* the whole document *<br>----- | 1-10,15, 16,18 | |
| | | | TECHNICAL FIELDS SEARCHED (Int.Cl.6) |

EPO FORM 1503 03.82 (P04C10)

European Patent Office

Application Number
EP 97 30 8140

## CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescibed time limit. The present European search report has been drawn up for the first ten claims.

## LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☒ All further search fees have been paid within the fixed time limit. The present Eurpean search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

European Patent Office

## LACK OF UNITY OF INVENTION
## SHEET B

Application Number
EP 97 30 8140

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-9

   Spinal fixation assembly for seating, contouring, locking and fixing an spinal rod

2. Claims: 10-18

   Spinal fixation assembly comprising screw head receiving means for retaining a head of a screw therein